FDA 510(k) Premarket Notification

K984278 MAGNETIC RESONANCE DIAGNOSTIC DEVICE, AIRIS II

CLEARED

Dec 11, 1998
11 days to decision

K984278 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k984278/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 30, 1998
Decision date	Dec 11, 1998
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hitachi Medical Systems America, Inc.**
Location	Twinsburg, OH, US
Contact	JAMES JOCHEN ROGERS
510(k) history	100 submissions · 100 cleared · 1991-2017